REMARKS

Applicants supplement the Remarks made in their Amendment under 37 C.F.R. §1.116, filed April 4, 2008, with the following observations.

As argued in applicants' April 4, 2008 response, all the claims currently in this application, Claims 1, 3, 5, 7 and 11-14, are patentable, under 35 U.S.C. §103(a), over Collins taken in view of Beuls-Riché et al. However, applicants submit the following remarks, which add new arguments, in support of the contention.

The present application discloses that nemorubicin is metabolized in the liver by the CYP3A4 isoenzyme. The present invention exploits this fact to identify patients who could most benefit from nemorubicin administration. That is, the finding that the CYP3A4 isoenzyme converts nemorubicin into a more active metabolite predicates the method of the present application. That is, the discovery that a more active metabolite of nemorubicin is formed permits an improved treatment of liver cancer or a liver metastases.

This claimed process is not made obvious by the combined teaching of the applied references. The principal Collins reference teaches the ascertainment of CYP3A enzyme levels in order to exclude those patients who exhibit a propensity to rapidly eliminate docetaxel. Thus, Collins teaches that the CYP3A enzyme may be utilized to screen out patients who too rapidly metabolize docetaxel.

That is, although both the Collins test and the claimed method of the present application rely on the metabolizing effect of the CYP3A enzyme, different metabolizing effects are measured and exploited. In the claimed method of the present application a test to identify patients who would benefit from treatment with nemorubicin is provided. Collins, on the other

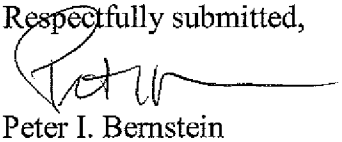
hand, teaches the method of eliminating patients for whom treatment with docetaxel would be futile, due to its rapid metabolism by CYP3A in the liver.

In summary, the only commonality between the method of Claims 1, 3, 5, 7 and 11-14 and the teaching of Collins is that they share the use of CYP3A to determine its metabolic effect on two different chemotherapeutic agents. However, this is not enough to present a prima facie case of obviousness given that the claimed method of the present application is employed to identify patients who benefit from treatment with a chemotherapeutic agent, nemorubicin, which is effective in treating liver cancers and metastases, whereas the prior art Collins teaching identifies patients who do not benefit from treatment with a distinguished chemotherapeutic agent, docetaxel, in the treatment of those diseases.

For this reason, as well as the reasons included in the Remarks section of the earlier April 4, 2008 Amendment under 37 C.F.R. §1.116, reconsideration and removal of the substantive grounds of rejection of the claims currently in this application is deemed appropriate. Such action is respectfully urged.

The above remarks establish the patentable nature of all the claims currently in this application. Notice of Allowance and passage to issue of these claims, Claims 1, 3, 5, 7 and 11-14, is therefore respectfully solicited.

Respectfully submitted,



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